

9.0 APPENDIX A: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: May 9, 2003

510(k) number: _____

Applicant Information:

Kerberos Proximal Solutions, Inc.
1400 Terra Bella Ave
Suite K
Mountain View, CA 94043

Contact Person: Tom Mason
Phone Number: (650) 254-1005
FAX Number: (650) 254-1034

Device Information:

Classification: Class II
Trade Name: KPS Rinspiration™ System
Classification Name: Catheters, Intravascular, Diagnostic (21 CFR 870.1200)

Predicate Device:

The subject device is substantially equivalent in intended use and/or method of operation to a combination of the Merit Medical Fountain Infusion System (K974067/K981417), the Mallinckrodt Guiding Catheter (K873004) and the OriGen Dual Lumen Catheter (K003288).

Intended Use:

The KPS Rinspiration™ System is intended to infuse and aspirate in the peripheral vasculature.

Device Description:

The system consists of a Rinspiration™ Catheter and a KPS Rinspirator™ and its accessories. The KPS Rinspiration™ Catheter is a multi-lumen catheter that has perforations located near the distal end of the catheter to dispense an infusible fluid. The Rinspiration™ Catheter will be placed in the peripheral vasculature of a patient over a guide wire. The Rinspiration™ Catheter is available in over the wire and rail configurations. The catheter includes a radiopaque marker band at the distal tip and two radiopaque marker bands designating the infusion portion of the catheter. The catheter has a hub on the proximal end that allows access to the infusion and aspiration lumens. The KPS Rinspirator™ and its accessories is a sterile, single-use mechanical device. This hand-activated device allows for simultaneous irrigation and aspiration of the treatment site. The device activates two syringes for infusion and aspiration. This action is known as "Rinspiration™."

Functional Test Results:

Results of bench testing demonstrate that the KPS Rinspiration™ System is safe and effective for its intended use.

Biocompatibility:

The materials used in the KPS Rinspiration™ System have been shown to be biocompatible when tested in accordance with ISO 10993-1 Biological Evaluation of Medical Devices -- Part 1: Evaluation and testing requirements.

Summary:

Based on the intended use, product performance and biocompatibility information provided in this notification, the subject device has been shown to be substantially equivalent to currently marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 25 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kerberos Proximal Solutions
c/o Mr. Tom Mason
1400 Terra Bella, Suite K
Mountain View, CA 94043

Re: K031485
KPS Rinspiration™ System
Regulation Number: 21 CFR 870.1200
Regulation Name: Catheter, Intravascular, Diagnostic
Regulatory Class: Class II (two)
Product Code: DQO
Dated: July 22, 2003
Received: July 23, 2003

Dear Mr. Mason:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

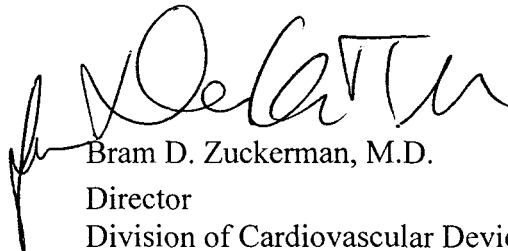
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Bram D. Zuckerman', is written over the typed name.

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number: K031485

Device Name: KPS Rinspiration™ System

Indications for Use:

The KPS Rinspiration™ System is intended to infuse and aspirate in the peripheral vasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON
ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K031485

Prescription Use X
(Per 21 CFR 801.109)

OR

Over the Counter Use _____
(Optional Format 1-2-96)